K101831

BIONOSTICS
Quality Solutions

510(k) Summary[1]

OCT 1 2010

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Minna Rannikko
Director, R&D
(978) 772-7070 x 236

Date of preparation of this summary: 28 September 2010

(2) Device trade or proprietary name: Enterix® InSure® FIT™ FOBT Controls

Device common or usual name or classification name:

GGM Hematology Quality Control Mixture
Sub class: OSL, Control Fecal Occult Blood

REGULATION MEDICAL SPECIALTY	REGULATION NUMBER	CLASS	REGULATION DESCRIPTION
Hematology	864.6550	II	Occult Blood Test

I. Substantial Equivalence

Enterix InSure FIT FOBT Control Solution is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use as shown in the following tables. Clearview Ultra FOB Kit and Hemoccult ICT FOB Test Kits were qualified per manufacturer's instructions using respective positive and negative controls.

Product	Enterix InSure FIT FOBT Negative Control	Clearview® Ultra FOB Negative Control	Hemoccult® ICT FOB Negative Control
510(k), Date	K101831, tbd	K041297, 12 Aug 2004	K080812, 25 Jun 2008
Net Fill	1.5 mL	1.0 mL	0.8 ml
Analyte	hemoglobin	hemoglobin	hemoglobin
Hemoglobin Concentration	zero	zero	zero
Container	3 mL plastic dropper vial	3 mL plastic dropper vial	3 mL plastic dropper vial
Matrix	aqueous	aqueous	aqueous
Result on Enterix InSure FIT Kit	Negative test line Positive control line	---	---

Table5.1: Comparison of Features – Negative Controls

ENTERIX and INSURE are registered trademarks of Enterix, Inc., Fernwood, NJ, USA.
CLEARVIEW is a registered trademark of Inverness Medical Switzerland GmbH, Zug Switzerland.
HEMOCCULT is a registered trademark of Beckman Coulter, Inc., Brea, CA, USA.
[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Product	Enterix InSure FIT FOBT Positive Control	Clearview Ultra FOB Positive Control	Hemoccult ICT FOB Positive Control
510(k), Date	K101831, tbd	K041297, 12 Aug 2004	K080812, 25 Jun 2008
Net Fill	1.5 mL	1.0 mL	0.8 ml
Analyte	hemoglobin	hemoglobin	hemoglobin
Container	3 mL plastic dropper vial	3 mL plastic dropper vial	3 mL plastic dropper vial
Matrix	aqueous	aqueous	aqueous
Result on Enterix InSure FIT Kit	Positive test line Positive control line	---	---

Table5.2: Comparison of Features – Positive Controls

II. Description of the new device

Enterix InSure FIT FOBT Controls is a two-level, aqueous control solution. **Enterix InSure FIT FOBT Controls** is intended for use to verify the performance of Enterix InSure FIT product. The Enterix InSure FIT Test method is based on the detection of human hemoglobin (hHb). Human hemoglobin indicates the presence of blood in the stool. The test detects the globin (protein) portion of the hHb molecule. Because globin does not survive passage through the upper gastrointestinal (GI) tract, any globin in the stool indicates that there is bleeding in the lower colon or rectum, the region where colorectal cancers originate. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips.

Enterix InSure FIT FOBT Controls is a non-hazardous aqueous solution containing bovine albumin, salts, buffers preservatives and in addition contains human hemoglobin in the positive control.

(a) (1) Intended use of the device

Enterix InSure FIT FOBT Controls are for in vitro diagnostic use only and include a positive control containing stabilized human hemoglobin and a negative control containing a buffer. This is an assayed positive and negative control and intended for the qualitative test determinations of Enterix InSure FIT product. Enterix InSure FIT FOBT Controls are for exclusive use with Enterix InSure FIT product. These controls can be used to independently verify the functionality and performance of the InSure FIT test by laboratories and other professional medical institutions as part of a comprehensive quality assurance program.

(a) (2) Technological characteristics of the device.

This material consists of aqueous control solution prepared at two concentrations of hemoglobin and has been optimized to simulate the response of fecal occult blood samples on the Enterix InSure FIT Product. The solution contains bovine albumin, salts, buffers preservatives and in addition contains human hemoglobin in the positive control.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability (Shelf-life)
b) Stability after opening (Use-life)
c) Transport Stability
d) Test response

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.
N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Bionostics, Inc.
c/o Ms. Minna Rannikko
Director, Research and Development
7 Jackson Road
Devens, MA 01434

OCT 01 2010

Re: k101831
Trade/Device Name: Enterix® Insure® FIT™ FOB Controls
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: OSL
Dated: August 18, 2010
Received: August 24, 2010

Dear Ms. Rannikko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of

substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

For Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K101831

Device Name: Enterix® InSure® FIT™ FOBT Controls

Indications for Use: Enterix InSure FIT FOBT Controls are for in vitro diagnostic use only and include a positive control containing stabilized human hemoglobin and a negative control containing a buffer. This is an assayed positive and negative control and intended for the qualitative test determinations of Enterix InSure FIT product. Enterix InSure FIT FOBT Controls are for exclusive use with Enterix InSure FIT product. These controls can be used to independently verify the functionality and performance of the InSure FIT test by laboratories and other professional medical institutions as part of a comprehensive quality assurance program.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K101831